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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,035	10/31/2003	John Francis Bateman	A36056-PCT-USA-A	3842

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,035	BATEMAN ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is noted:

   A. Claims 35 and 36 are duplicates of each other.

   B. Claims 38 and 39 recite genetically modified animal but depend from an antibody claim 34.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

   I. Claims 1-14, drawn to an isolated polypeptide, a derivative or homolog thereof of WARP; classified in Class 530, subclasses 395, 837, and 866.

   II. Claims 15-24, drawn to an isolated nucleic acid molecule or a derivative or homolog thereof of WARP encoding a polypeptide, and a method of producing; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3.

   III. Claims 25-27, drawn to a method for identifying a nucleotide sequence likely to encode a WARP, comprising interrogating an animal genome database conceptually translated into different reading frame with an amino acid sequence defining a VA domain and identifying a nucleotide sequence corresponding to a sequence encoding said VA domain, classified in Class 707, subclass 3.

   IV. Claim 29, drawn to a method for monitoring repair, regeneration or other disease processes by screening body fluid from said animal for the presence of a WARP or fragment thereof, classified in Class 435, subclass 7.1.

   V. Claim 30, drawn to a method for detecting a disease condition or a propensity for the development of a disease comprising screening body fluid for the presence of a WARP or fragment thereof, classified in Class 435, subclass 7.1.

   VI. Claims 31-36, drawn to an isolated antibody; classified in Class 530, subclass 387.3, and 391.1.

   VII. Claims 37-39, drawn to a genetically modified animal comprising a modification to a gene encoding a WARP polypeptide, classified in Class 800, subclass 8.

   VIII. Claims 40-42, drawn to a target vector for inactivating a gene encoding WARP comprising two segments of genetic material encoding said WARP flanking a positive selectable marker, classified in Class 435, subclass 320.1.

Claim 28 links inventions IV and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 28. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Groups I-II and VI-VIII are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides, genetically modified animals and vectors differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

4. Groups III-V are different methods. A method of detecting, a method for monitoring and a method of identifying differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I is elected, applicant is required to elect either a) a polypeptide of human WARP of SEQ ID NO: 6 encoded by SEQ ID NO: 5 and the VA domain of SEQ ID NO: 2 encoded by SEQ ID NO:1 **OR** b) a polypeptide of murine WARP of SEQ ID NO: 4 encoded by SEQ ID NO: 3 and the VA domain of SEQ ID NO: 8 encoded by SEQ ID

NO: 7. These sequences are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If Group II is elected, applicant is required to elect a nucleic acid molecule of either a) a human WARP nucleic acid molecule of SEQ ID NO: 5 or 19 encoding SEQ ID NO: 6 and VA domain of SEQ ID NO: 1 encoding SEQ ID NO: 2 **OR** b) a murine WARP nucleic acid molecule of SEQ ID NO: 3 encoding SEQ ID NO: 4 and A VA domain of SEQ ID NO: 7 encoding SEQ ID NO: 8. These sequences are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

C. If Group VI is elected, applicant is required to elect an antibody that specifically binds either a) a polypeptide of human WARP of SEQ ID NO: 6 encoded by SEQ ID NO: 5 and the VA domain of SEQ ID NO: 2 encoded by SEQ ID NO:1 **OR** b) a polypeptide of murine WARP of SEQ ID NO: 4 encoded by SEQ ID NO: 3 and the VA domain of SEQ ID NO: 8 encoded by SEQ ID NO: 7. These sequences are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

D. If Group VII is elected, applicant is required to elect a genetically modified animal, wherein the animal either a) overexpresses **OR** lacks a functional expression of a gene of either a) a human WARP nucleic acid molecule of SEQ ID NO: 5 or 19 encoding SEQ ID NO: 6 and VA domain of SEQ ID NO: 1 encoding SEQ ID NO: 2 **OR** b) a murine WARP nucleic acid molecule of SEQ ID NO: 3 encoding SEQ ID NO: 4 and A VA domain of SEQ ID NO: 7 encoding SEQ ID NO: 8. These sequences are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 4, 2005

Maher Haddad

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